

State/Territory: MICHIGAN

STANDARDS FOR THE COVERAGE OF ORGAN TRANSPLANT SERVICES

Liver, heart, heart/lung, bone marrow, and pancreas transplants are reviewed on a case-by-case basis for coverage.

Each request for coverage is considered by a committee of physician experts, and is judged as to the appropriateness of the transplantation procedure for funding. The committee uses a list of patient selection criteria to assist in making this judgement. The criteria are maintained for all organ extrarenal transplants, and are periodically revised. These criteria are used as guidelines. No set of written criteria can completely anticipate all the possible circumstances that may be associated with each individual case. The criteria were developed by the Michigan Department of Public Health and are as follows:

I. Heart Transplant

A. Indications for heart transplant

1. Absolute indications

- a. NYHA Class IV cardiac disease, without surgically correctible mechanical defects and unresponsive to medical therapy.
- b. A fixed pulmonary vascular resistance below eight Wood units.
- c. A thorough understanding by the patient and family of the magnitude of the operation and its sequelae, including lifetime follow-up.
- d. Strong motivation by the patient to undergo the procedure.
- e. A reasonable expectation that the patient's quality of life will be improved.
- f. Medical assessment that the patient is a reasonable risk for operation and has a tolerance of immuno-suppressive therapy.
- g. Medical assessment that the patient has sufficient social stability to provide assurance that he or she will cooperate with the follow-up and the immuno-suppressive program.

2. Relative indications

- a. Not older than 55 years of age

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B. Contraindications to heart transplant

1. Absolute contraindications

- a. Active infection, including dental infection.
- b. Active peptic ulcer disease.
- c. Cancer, unless evidence indicates that there is a high probability that the cancer is cured.
- d. Substance abuse, including ethanol and narcotic addiction.
- e. Significant irreversible mental disorder.
- f. Severe generalized arteriosclerosis.
- g. Chronic bronchitis or severe chronic obstructive pulmonary disease (COPD).

2. Relative contraindications

- a. Insulin dependent diabetes.
- b. Recent pulmonary embolism.
- c. Morbid obesity.

II. Heart/lung transplant

A. Indications for heart/lung transplant

1. Absolute indications

- a. NYHA class IV cardiac disease, without surgically correctible mechanical defects and unresponsive to medical therapy, with secondary lung damage leading to a fixed pulmonary vascular resistance of at least eight Wood units.
- b. Severe terminal pulmonary disease unresponsive to all medical therapy, for example chronic emphysema, cystic fibrosis, pulmonary fibrosis, or congenital defects.
- c. A thorough understanding by the patient and family of the magnitude of the operation and its sequelae, including lifetime follow-up.
- d. Strong motivation by the patient to undergo the procedure.
- e. A reasonable expectation that the patient's quality of life will be improved.
- f. Medical assessment that the patient is a reasonable risk for operation and has a tolerance of immunosuppressive therapy.
- g. Medical assessment that the patient has sufficient social stability to provide assurance that he or she will cooperate with the follow-up and the immunosuppressive program.

2. Relative indications

- a. Not older than 40 years of age.

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B. Contraindications to heart/lung transplant

1. Absolute contraindications

- a. Active infection, including dental infection.
- b. Active peptic ulcer disease.
- c. Cancer, unless evidence indicates that there is a high probability that the cancer is cured.
- d. Substance abuse, including ethanol and narcotic addiction.
- e. Significant irreversible mental disorder.
- f. Severe generalized arteriosclerosis.

2. Relative contraindications

- a. Insulin dependent diabetes.
- b. Morbid obesity.

III. Liver transplant

A. Indications for liver transplant

1. Absolute indications

- a. Irreversible chronic liver disease which has progressed to the point of significant interference with the patient's ability to work or quality of life, and for which no effective medical or surgical therapeutic alternative is available.
- b. A thorough understanding by the patient and family of the magnitude of the operation and its sequelae, including lifetime follow-up.
- c. Strong motivation by the patient to undergo the procedure.
- d. A reasonable expectation that the patient's quality of life will be improved.
- e. Medical assessment that the patient is a reasonable risk for operation and has a tolerance of immunosuppressive therapy.
- f. Medical assessment that the patient has sufficient social stability to provide assurance that he or she will cooperate with the follow-up and the immunosuppressive program.

2. Relative indications

- a. Not older than 50 years of age.
- b. Stable patient with history of a failed hepatic transplant.
- c. A specific liver disease state characterized by
 - 1) Albumin less than 2.0 gm/dl.
 - 2) Serum bilirubin greater than 15 mg/dl.

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B. Specific disease states for liver transplant

1. Alcoholic cirrhosis if the patient has abstained for two years as documented by multidisciplinary institutional review.
2. Budd-Chiari syndrome.
3. Caroli's disease.
4. Chronic active hepatitis (HBsAg negative)
5. Congenital hepatic fibrosis.
6. Cryptogenic cirrhosis.
7. Extrahepatic biliary atresia with or without prior portoenterostomy.
8. Hepatic adenomatosis.
9. Inborn errors of metabolism:
 - a. Alpha-1-antitrypsin deficiency (ZZ phenotype).
 - b. Byler's disease.
 - c. Crigler-Najjar syndrome, Type I.
 - d. Galactosemia.
 - e. Glycogen storage disease, Type I and IV.
 - f. Hemachromatosis.
 - g. Protoporphyrria.
 - h. Sea blue histiocyte syndrome.
 - i. Trysinemia.
 - j. Wilson's disease.
 - k. Other rare diseases considered on a case-by-case basis.
10. Neonatal hepatitis.
11. Pediatric hepatoblastoma and other primary hepatic tumors of low grade malignancy.
12. Portal hypertension requiring a portan decompressive procedure concomitant with end-stage liver disease.
13. Post-hepatic cirrhosis.
14. Primary biliary cirrhosis.
15. Sclerosing cholangitis.
16. Secondary biliary cirrhosis.
17. Subacute hepatic necrosis.

C. Contraindicators to liver transplant

1. Absolute contraindications

- a. Active infection, including dental infection.
- b. Active peptic ulcer disease.
- c. Anasarca.
- d. Cancer, unless evidence indicates that there is a high probability that the cancer is cured; pediatric hepatoblastoma is an exception.
- e. Hepatitis B surface and e antigen positivity.
- f. Portal vein thrombosis.
- g. Severe generalized arteriosclerosis.
- h. Severe irreversible coagulopathy.
- i. Severe life-limiting associated extrahepatic disease.
- j. Substance abuse, including ethanol and narcotic addiction.
- k. Significant irreversible mental disorder.

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2. Relative contraindications

- a. Hepatitis B surface antigen positivity without e antigen positivity.
- b. Insulin dependent diabetes mellitus.
- c. Intrahepatic or biliary sepsis.
- d. Morbid obesity.

IV. Pancreatic transplant

A. Indications for pancreatic transplant

1. Absolute indications

- a. Irreversible severe diabetes mellitus which has progressed to the point of significant interference with the patient's ability to work or quality of life, and for which no effective medical or surgical therapeutic alternative is available.
- b. A thorough understanding by the patient and family of the magnitude of the operation and its sequelae, including lifetime follow-up.
- c. Strong motivation by the patient to undergo the procedure.
- d. A reasonable expectation that the patient's quality of life will be improved.
- e. Medical assessment that the patient is a reasonable risk for operation and has a tolerance of immunosuppressive therapy.
- f. Medical assessment that the patient has sufficient social stability to provide assurance that he or she will cooperate with the follow-up and the immunosuppressive program.

2. Relative indications

- a. Between 5 years and 50 years of age.
- b. Presence of a complication of diabetes: retinopathy, neuropathy, renal failure, gastroenteropathy.
- c. Inability to obtain a reasonable control of blood sugar with conventional treatment.

B. Specific disease states for pancreatic transplant

1. Type I insulin-dependent diabetes.
2. Insulin dependent diabetes secondary to traumatic or surgical removal of pancreas.

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C. Contraindications to pancreatic transplant

1. Absolute contraindications

- a. Active infection, including dental infection.
- b. Active peptic ulcer disease.
- c. Cancer, unless evidence indicates that there is a high probability that the cancer is cured.
- d. Severe uncorrectable coronary artery disease.
- e. Substance abuse, including ethanol and narcotic addiction.
- f. Significant irreversible mental disorder.

2. Relative contraindications

- a. Morbid obesity.

V. Bone marrow transplant

A. Indications for bone marrow transplant

1. Absolute indications

- a. Specific bone marrow disease states, with a performance status of 2 or less on the ECOG scale.
- b. A thorough understanding by the patient and family of the magnitude of the operation and its sequelae, including lifetime follow-up.
- c. Strong motivation by the patient to undergo the procedure.
- d. A reasonable expectation that the patient's quality of life will be improved.
- e. Medical assessment that the patient is a reasonable risk for operation and has a tolerance of immunosuppressive therapy.
- f. Medical assessment that the patient has sufficient social stability to provide assurance that he or she will cooperate with the follow-up and the immunosuppressive program.

2. Relative indications

- a. Not older than 50 years of age for allogeneic BMT.
- b. Not older than 65 years of age for autologous BMT.

B. Specific disease states for bone marrow transplant

1. Leukemia: acute lymphocytic and non-lymphocytic leukemia, chronic myelogenous leukemia (in chronic or transformed stage).
2. Severe aplastic anemia.
3. Immune deficiency syndromes.
4. Steroid-resistant Blackfan-Diamond syndrome.
5. Fanconi's anemia.

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6. Lymphoma (high-risk group or in relapse).
7. Hodgkin's disease (resistant relapse).
8. Neuroblastoma (stage IV).
9. Congenital severe hemolytic anemias (pyruvate kinase deficiency or thalassemia major).
10. Hairy cell leukemia (persistent pancytopenia after splenectomy).
11. Myelodysplastic syndrome (with severe pancytopenia).
12. Chediak-Higashi syndrome.
13. Kostman's syndrome.

C. Contraindications to bone marrow transplant

1. Absolute contraindications

- a. Any major irreversible organ damage.
- b. Active infection, including dental infection.
- c. Active peptic ulcer disease.
- d. Substance abuse, including ethanol and narcotic addiction.
- e. Significant irreversible mental disorder.

2. Relative contraindications

- a. Morbid obesity.

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